

**K221114 Immunoglobulin G (IgG)**Aug 2, 2023  
474 days to decisionK221114 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k221114/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Apr 15, 2022
Decision date	Aug 2, 2023
Days to decision	474 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Beckman Coulter Laboratory Systems (Suzhou) Co., Ltd.</b>
Location	Suzhou, CN
Contact	Tracy Jin
510(k) history	2 submissions · 2 cleared · 2023-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221114/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026